

IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF
PENNSYLVANIA

UNITED STATES OF AMERICA,	:	NO. 3:16-CR-194
	:	
Plaintiff	:	
v.	:	(Judge Richard Caputo)
	:	
FUHAI LI,	:	
Defendant	:	

AMENDED REPLY BRIEF TO GOVERNMENT’S BRIEF IN OPPOSITION TO
DEFENDANT’S MOTION IN LIMINE TO EXCLUDE EXPERT OPINIONS AND
TESTIMONY

INTRODUCTION

On March 5, 2018, the defendant filed a motion to exclude Dr. Thomas' reports and his testimony at trial, which was accompanied by a brief in support of that motion filed on March 6, 2018. The government's response to defendant's motion to preclude Stephen M. Thomas, M.D. from providing expert testimony at trial was filed on March 13, 2018. Brief in Opposition by USA (March 13, 2018). In response to the brief in Opposition by the government, the defendant set up the following argument:

ARGUMENT

Federal Rule of Evidence 702 governs the admissibility of expert testimony as follows: A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

- (a) The expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issues;
- (b) The testimony is based on sufficient facts or data;
- (c) The testimony is the product of reliable principles and methods; and
- (d) The expert has reliably applied the principles and methods to the facts of the case.

Federal Rule of Evidence 702

Under the Rule 702, the task of "gatekeeping" rests on the trial judge. In determining the admissibility of an expert's opinion or testimony, the courts must review these three Daubert factors:

- (1) The expert's qualifications,
- (2) The reliable methods, principles or foundations the opinion or testimony is based on, and
- (3) The fit of the expert's methods to the facts of the case or relevancy to the task at hand. Rowland v. Novartis Pharmaceuticals Corp., 9F. Supp. 3d 553, 558-559 (U.S.D.C.W.D. Pa 2014). Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 584-587 (1993).

The expert's qualification is determined by his or her education, training, experience, knowledge or skill. The reliable methods, principles or foundations require that the expert's opinion or testimony truly proceeds from "scientific knowledge" which is the product of "scientific methodology". The court defines "scientific methodology" as the process of formulating hypothesis and the conducting experiments to prove or falsify the hypothesis, and provide a set of illustrative factors in determining whether these criteria are met: (a) whether the theory or technique employed by the expert is generally accepted in the scientific community; (b) whether it has been subjected to peer review and publication; (c) whether it can be and has been tested; (d) whether the known or potential rate of error is acceptable; and (e) whether the research was conducted independent of the particular litigation or dependent on an intention to provide the proposed testimony. Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311 (9th Cir. 1995)

In the instant case, the government misapplied and misunderstood these Daubert factors which determine the admissibility of an expert's testimony as evidenced by the following:

A. The crucial evidence to support his opinion was missed in Dr. Thomas' report.

As the government stated, Dr. Thomas was hired by the government "for the purpose of offering an opinion as to the medical legitimacy of the prescribing of opioids associated with those files, and whether such prescribing habits occurred within the course of professional practice." Brief in Opposition by USA (page 4). Therefore, the central inquiry in the current case was the scientific knowledge Dr. Thomas relied on to form his opinion that the Defendant's opioid prescriptions were not for a legitimate medical purpose, nor within the usual course of

professional practice. Both Dr. Thomas' report and the government's Brief in Opposition had never indicated that Dr. Thomas specifically cited any scientific knowledge in the medical community such as clinical practice guidelines, the Federation of State Medical Boards model policies or peer reviewed publications as evidence to support his opinion or to explain why the defendant's opioid prescriptions were not for a legitimate medical purpose or not within the usual course of professional practice.

B. The government misapplied the Daubert factors.

1. Qualification is not the evidence of scientific knowledge to support Dr. Thomas' opinion

The government stated that "Additionally, Dr. Thomas offered his opinions based on his education and experience as a Board Certified Anesthesiologist with a subspecialty in Pain Management; a Diplomat of the American Board of Anesthesiology and Pain Medicine; a Fellow of Interventional Pain Practice; Certifications held in controlled substance Management, Coding Compliance and Practice Management, and as an Independent Medical Examiner; his more than 30 years as a practicing physicians; as well as numerous highly regarded appointments, positions, certifications, lectures, publications, honors and awards. In addition, Dr. Thomas has previously been qualified to testify as an expert in pain management in both federal and state courts throughout the country." Brief in Opposition by USA (page 4-5). The government further stated that "Dr. Thomas' reports evidence a scientifically objective opinion based upon the practice of medicine, and specifically the practice of writing prescriptions for the powerful opioid medications." Brief in Opposition by USA (page 9). These statements are related to Dr. Thomas' qualification which the defendant did not dispute. Qualification is one of the Daubert

factors, but it is not the scientific evidence Dr. Thomas can rely on to support his opinion that the defendant's opioid prescriptions were not for a legitimate medical purpose or not within the usual course of professional practice. The opinion of an expert, no matter how qualified he or she is, cannot simply be based on his or her say so. "[N]othing in either Daubert or the Federal Rule of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert." *General Electric Co. v. Joiner*, 522 U. S. 136, 146 (1997).

2. Dr. Thomas' methodology about how to review medical records was not evidence of scientific knowledge to support Dr. Thomas' opinion.

The government stated that "In the report, Dr. Thomas details the methodology he employed in the assessment;" Brief in Opposition by USA (page 4). The government further cited the methodology used by Dr. Thomas in reviewing the medical records:

- 1) Each medical record submitted was read in its entirety;
- 2) The medical record was assessed for its completeness in outlining the indication for the prescription of the controlled substance, including diagnosis as ascertained through history, physical examination and diagnostic testing;
- 3) For chronic pain prescriptions the regularity of the prescribing pattern was observed;
- 4) Gross omissions from the medical record were discerned;
- 5) The indication or lack of indication for changes in dose were ascertained when possible;
- 6) Efforts to monitor the medication-taking behavior of the patients were considered." Brief in Opposition by USA (page 9). In fact, this so-called methodology demonstrates only how he reviewed the medical records, which has nothing to do with what was

the scientific knowledge Dr. Thomas relied on to form his opinion that the defendant's opioid prescriptions were not for a legitimate medical purpose or not within the usual course of professional practice (i.e. irrelevant to the task at hand).

3. The federal regulation, the Pennsylvania Controlled substances, Drugs, Device and Cosmetics Act, and Pennsylvania Code are not evidence of scientific evidence or standards to support Dr. Thomas' opinion.

The government stated that "the laws applicable to physicians licensed by the Commonwealth of Pennsylvania relied upon in reaching his conclusions; applicable federal regulations relied upon;" Brief in Opposition by USA (page 4). The government further cited the applicable laws and regulations Dr. Thomas applied: "[T]he federal regulation, 21 C.F.R. 306.04 (a) Purpose of issue of prescription, was the primary guide used in the medical record review. The regulation calls for the issuance of controlled substance prescriptions for a 'legitimate medical purpose'.... The Pennsylvania Controlled substances, Drugs, Device and Cosmetics Act provided additional guidance as to the legitimate medical purpose of a prescription for controlled substances in that the substance must be provided in the usual course of the physician's professional practice, within the scope of a doctor-patient relationship, and in accordance with the accepted treatment principles of any responsible segment of the medical community...Additionally, Pennsylvania Code, Title 41 16.92 provided the documentation requirements for controlled substances for physicians in the Commonwealth." Brief in Opposition by USA (page 8). These are not scientific knowledge Dr. Thomas can rely on to form his opinion that the defendant's prescriptions were not for a legitimate medical purpose or not within the usual course of professional practice. These are only the governing statutes stating that it is unlawful if the prescriptions issued are not for a legitimate medical purpose or not within the

usual course of professional practice or not in accordance with the accepted treatment principles in the medical community. The laws or regulations themselves do not define "legitimate medical purpose", "within the usual course of professional practice" or "in accordance with the accepted treatment principles in the medical community." Consequently, they cannot be used as evidence to determine whether or not the defendant's prescriptions were for a legitimate medical purpose or within the usual course of professional practice. In other words, they have nothing to do with scientific knowledge Dr. Thomas could rely on to form his opinion (i.e. irrelevant to the task at hand). "Legitimate medical purpose", "within the usual course of professional practice" and "accepted treatment principles" of opioid treatment for non-cancer pain are medically related questions and are defined by evidence in the medical community such as clinical practice guidelines, medical board model policies or peer reviewed publications as illustrated in the defendant's motion in limine (Defendant's motion in limine to exclude the expert opinions and testimony of Dr. Stephen Thomas (March 5, 2018)), which are scientific evidence or written standard to determine whether the opioid prescriptions are for a legitimate medical purpose and within the usual course of professional practice.

4. Dr. Thomas failed to cite specific publications he relied on to form his opinion

The government mentioned about possible publications in such a way that "he references his reliance on various studies and research associated with pain management beginning in the mid-1980s." Brief in Opposition by USA (page 4). However, this is not enough to be evidence of scientific knowledge Dr. Thomas relied on to form his opinion without citing specific studies or peer reviewed publications. Rowland v. Novartis Pharmaceuticals Corp., 9F. Supp. 3d 553, 558-559 (U.S.D.C.W.D. Pa 2014). Citing Daubert at 594-95. The expert's opinion must be supported by specific written standard before it is admitted to evidence in the court as a trial court pointed

out: "They must specifically cite the written standard they are relying on or provide testimony as to the accepted standard in the field." United States v. Zolot and Pliner, 968 F. Supp. 2d 411 (2013).

C. The government's other meritless points to explain Dr. Thomas' report.

When the government failed to provide scientific knowledge Dr. Thomas's opinion was based on, the government tried different ways. The government then stated that "To be clear, the reports are not themselves evidence nor does the Government contemplate that the reports will simply be provided to the jury. The purpose of the reports is to give fair notice to the defendant about expert opinions, as required by Rule 16." Brief in Opposition by USA (page 5). The government is wrong. The defendant strongly believes that Dr. Thomas' reports had been used as important evidence to indict the defendant by the grand jury, although his opinion in the reports had no scientific basis. Furthermore, Dr. Thomas's reports or opinion in the reports and further testimony should be simply excluded as the government itself admitted that the reports are not themselves evidence.

The government further stated that "The reports unquestionably comply with the Federal Rules and the Government should not be required to preview for the defendant how it is that the qualified expert will ably defend against the defendant's baseless attacks. Brief in Opposition by USA (page 5). The Government is wrong in two folds. First, the reports failed to comply with the Federal Rule of Evidence 702 which requires that the opinion in the reports must be based on scientific knowledge. Second, the defendant's attack on the government's expert was based on

factual evidence set forth in the motion in Limine as "IV. ARGUMENT TO DR. THOMAS'S REPORT AND CONCLUSION," which clearly and factually states that:

(1) Dr. Thomas's report was not an independent review of medical records and was biased. Therefore the "scientific methodology" used to produce his conclusion was flawed;

(2) Dr. Thomas inserted information in his report which was not in the medical record;

(3) Dr. Thomas failed to glean relevant facts from medical records to draw conclusion;

(4) Dr. Thomas made substantial false statements in his report of medical record review;

(5) Dr. Thomas either applied unreliable principles, irrelevant facts or false statements to draw his conclusion or drew his conclusion based on his own say so; and

(6) Disputed opinion or negligence was not evidence that opioid prescriptions were not for a legitimate medical purpose or not within the usual course of professional practice.

Defendant's motion in limine to exclude the expert opinions and testimony of Dr. Stephen Thomas (March 5, 2018). As a matter of fact, the government failed to rebut all of these factual evidence, indicating government's concession.

The government further stated that "All of the defendant's attacks on Dr. Thomas' reports are of the type properly made during cross-examination of the expert, and not via a wholesale exclusion of relevant information from the jury's purview." Brief in Opposition by USA (page 5-

6). It is true that cross-examination will keep the admissible but shaky evidence out. However, the expert's report or opinion in the report must be scrutinized by the trial court to determine whether the expert's opinion is based on scientific knowledge or reliable foundation before it is admitted to the trial court under the Federal Rule of Evidence 702. The inadmissible or unsupported opinion should not be allowed into the trial court for cross-examination as required by Daubert standard (Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993)) and Federal Rule of Evidence 702. An unsupported opinion can offer no assistance to the fact finder and should not be admitted as expert testimony. Robertson III, 77 So.3d at 355.

Finally, the government stated that "Fundamentally, the defendant simply disagrees with Dr. Thomas' conclusion about the highly unprofessional and even dangerous practices that the defendant undertook and oversaw at his opioid prescribing practice." Brief in Opposition by USA (page 3). The government is wrong. As stated in the defendant's motion in limine, what the defendant disputed was that Dr. Thomas either used unreliable principles, irrelevant facts or false statements to draw his conclusion or drew his conclusion based on nothing but his own say so. Defendant's motion in limine to exclude the expert opinions and testimony of Dr. Stephen Thomas (March 5, 2018). Regardless of his conclusion, the fundamental point is that Dr. Thomas' opinion of whether the defendant's opioid prescriptions were for a legitimate medical purpose and within the usual course of professional practice must be based on scientific knowledge in the medical community such as clinical practice guidelines, medical board model policies or peer reviewed publications in order to be admitted to the trial court as evidence.

D. The government misunderstood Daubert factors about admissibility of an expert's opinion.

The government stated that "In addition, furthering the rule's liberal policy of accepting expert testimony, the Committee explained that even expert testimony 'not rely[ing] on anything like a scientific method' may be admissible, if 'it is properly grounded, well-reasoned, and not speculative'." The government is wrong. When there is no any scientific method available in the literature relevant to the task at hand, the expert testimony may be admissible without relying on such a scientific method if 'it is properly grounded, well-reasoned, and not speculative'. "Experts may testify on the basis of experience." Brown v. Wal-Mart Stores, Inc., 402 F. Supp. 2d 303, 308 (D. Me. 2005). However, "if the [expert] witness is relying solely or primarily on experience, then the witness must explain how that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Id. (Fed. R. Evid. 702 advisory committee's note). However, this is not the situation in our case where many relevant scientific evidence exists in the literature, which should be cited by Dr. Thomas to support his opinion. Furthermore, there is no evidence to support that Dr. Thomas' opinion in the report was properly grounded and well-reasoned. On the contrary, his opinion in fact was speculative and contradictory from case to case. The gatekeeping function of the trial court requires more than merely "taking the expert's word for it." Fed. R. Evid. 702 advisory committee's note (Daubert v. Merrell Dow Pharms., Inc., 43 F 3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the experts' qualifications, their conclusion and their assurances of reliability. Under Daubert, that's not enough.").

E. Dr. Thomas' opinion in his reports was unsupported by scientific knowledge, thus subjective in nature.

As the government indicated that "the Supreme Court held that scientific evidence is admissible in federal court if it is 'reliable'.... But, in order to qualify as 'scientific knowledge,' an

inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation-i.e. 'good grounds,' based on what is known." Brief in Opposition by USA (page 6-7). Thus, the government agreed with the defendant that the proposed testimony must be supported by "good grounds" which should be scientific knowledge under Daubert standard and Federal Rule of Evidence 702. Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311 (9th Cir. 1995). In our case, there are existing scientific knowledge such as the Federation of State Medical Boards model policies, clinical practice guidelines or peer reviewed publications regarding the "legitimate medical purpose", "within the usual course of professional practice" and "accepted treatment principle" of opioid treatment for chronic non-cancer pain as stated in the defendant's motion in limine. Defendant's motion in limine to exclude the expert opinions and testimony of Dr. Stephen Thomas (March 5, 2018). Dr. Thomas should review and cite these scientific knowledge to support his opinions. However, he chose to ignore these existing scientific knowledge and cited nothing or something irrelevant to the task at hand (such as his own so-called methodology to review medical records, federal regulation, the Pennsylvania Controlled substances, Drugs, Device and Cosmetics Act, and Pennsylvania Code) to support his opinions that the defendant's opioid prescriptions were not for a legitimate medical purpose.

The government stated that "It is clear from the actual written reports that the conclusions reached by Dr. Thomas are not subjective in nature. Rather, his methodology is based upon an understanding of what renders a prescriptions valid under the laws of the Commonwealth of Pennsylvania and federal regulations, as well as his medical knowledge of chronic pain, controlled substances, and the interplay between the two." The government is wrong. The conclusions reached by Dr. Thomas are exactly subjective in nature as such conclusions are not

based on any scientific knowledge in the medical community but based on the laws of the Commonwealth of Pennsylvania and federal regulations, as well as his medical knowledge as claimed by the government, which are not the scientific evidence he could rely on to form his opinion that the defendant's opioid prescriptions were not for a legitimate medical purpose or not within the usual course of professional practice as described above. It is very clear that his opinions in the reports were based on his only subjective belief which had nothing to support, and he would just simply cite that scientific knowledge in the medical community to support his opinions if he had one.

F. Opinion unsupported by scientific knowledge must be excluded.

The government stated that "There are no similarities, factual or legal, between the facts of Pritchard and the facts of this case." Brief in Opposition by USA (page 14). The government is right in the sense that at least two studies despite being unreliable were cited to support the expert's opinion in Pritchard (Prichard v. Agro Sciences, 430 Fed. Appx. 102 (3d Cir 2011)), but in the instant case, nothing relevant or something irrelevant (such as his own so-called methodology to review medical records, applicable laws and regulations) was cited by Dr. Thomas to support his opinions that the defendant's opioid prescriptions were not for a legitimate medical purpose or not within the usual course of professional practice. Therefore, the fortune of Dr. Thomas's opinion should be at least the same as the expert's opinion in Pritchard, if not worse, which is that Dr. Thomas's opinion and testimony should be excluded. A similar case law has existed where the expert's opinion and testimony of whether the opioid prescriptions were for a legitimate medical purpose and within the usual course of professional practice were excluded when the pain management expert failed to cite specific written standard to support his or her opinion. United States v. Zolot and Pliner, 968 F. Supp. 2d 411 (2013). Even a reliable method

was cited, the expert was still prohibited from testimony at trial when there was a gap between the method and conclusion (i.e. the method is irrelevant to the task at hand). Samann IV, 755 F.Supp.2d at 248. Furthermore, the trial court's decision not to exclude expert testimony was reversed by the appellate court when the expert's opinion "was at most a working hypothesis, not admissible scientific 'knowledge.'" Tamraz v. Lincoln Elec. Co., 620 F.3d 665,667-68 (6th Cir. 2010).

G. A Daubert hearing is needed in the current case.

The government cited that "There is no requirement that the District Court always hold a Daubert hearing prior to qualifying an expert witness...." Brief in Opposition by USA (page 14). When record of the trial court demonstrates that there are sufficient evidence to make the decision of whether the expert's opinion should be admitted or not, a Daubert hearing is not required. In reviewing the denial of a Daubert evidentiary hearing, the appellate court required "a sufficiently developed record in order to allow a determination of whether the district court properly applied the relevant law." United States v. Nichols, 169 F.3d 1255 (10th Cir. 1999). However, when an expert's "testimony's factual basis, data, principles, methods, or their application are called sufficiently into question, the trial judge must determine whether the testimony has 'a reliable basis in the knowledge and experience of the relevant discipline.'" (quoting Daubert, 509 U.S. at 592, 113 S.Ct. 2786). See Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 119 S.Ct. 1167, 1175, 143 L.Ed.2nd 238 (1999). The trial court should hold a Daubert hearing when there is question regarding the admissibility of expert's testimony. "The district court convened a Daubert hearing to screen that proffer and ultimately rejected it based on a determination that the testimony failed to cross the Daubert threshold." Samaan IV, 755 F.

Supp.2d at 248-49. In our case, mitigating factor for a Daubert hearing exists since the expert's opinion of the government was based on no scientific knowledge in the medical community and was sufficiently into question. At least, the government or Dr. Thomas needs to explain to the trial court why he did not cite any existing scientific knowledge in the medical community to support his opinion when these scientific knowledge such as clinical practice guidelines, medical board model policies or peer reviewed publications are easily available to physicians and other publics. "If the [expert] witness is relying solely or primarily on experience, then the witness must explain how that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Id. (Fed. R. Evid. 702 advisory committee's note).

CONCLUSION

In summary, it is clear that the government misapplied and misunderstood the Daubert factors which determine the admissibility of Dr. Thomas' opinion that the Defendant's opioid prescriptions were not for a legitimate medical purpose or not within the usual course of professional practice. In fact, Dr. Thomas did not cite any scientific knowledge easily available in the medical community regarding opioid treatment of chronic non-cancer pain such as clinical practice guidelines, medical board model policies or peer reviewed publications as evidence to support his opinion. Therefore, the opinion in the reports was unsupported and just his own subjective belief which is not admissible evidence under Daubert standard and Federal Rule of Evidence 702. The defendant's motion in limine to exclude Dr. Thomas' expert opinion in his reports and testimony at trial should be respectfully granted or a Daubert hearing should be held as Dr. Thomas' opinion in his reports was sufficiently into question.

Respectfully submitted,

William Ruzzo

WILLIAM RUZZO, ESQUIRE
Attorney I.D. #75865
590 Rutter Avenue
Kingston, PA 18704
(570) 288-7799
Fax (570) 288-7798